

***IN THE UNITED STATES PATENT AND TRADEMARK OFFICE***

Applicant: ROSIELLO et al.  
Title: INTEGRAL SEAL FOR CENTRIFUGE CHAMBER  
Appl. No.: 10/723,499  
Filing Date: 11/25/2003  
Examiner: David L. Sorkin  
Art Unit: 1797  
Confirmation Number: 8935

**DECLARATION OF KEITH ROSIELLO UNDER 37 C.F.R. § 1.132**  
**TRAVERSING GROUNDS OF REJECTION**

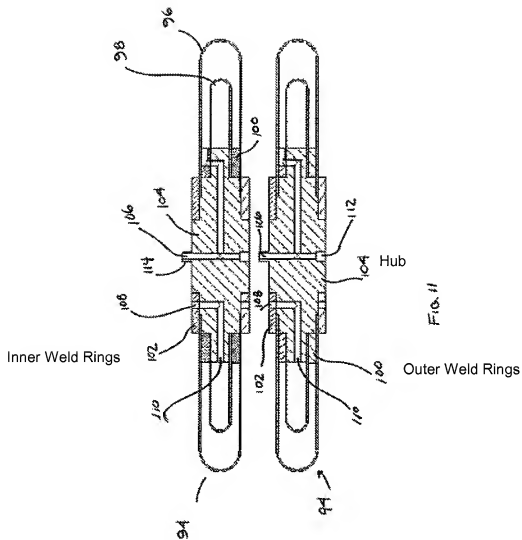
Under 37 C.F.R. § 1.132 and regarding the rejection of claims 11-6, 8-18, 20-30, 32-38, and 49-51 under 35 U.S.C. §§ 102(b) and 103, as being anticipated by and/or unpatentable over Jorgensen et al. (US 2002/0107131), I declare:

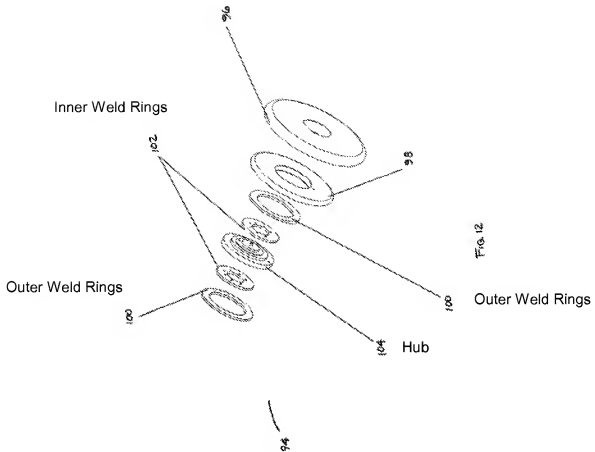
1. I am an inventor of the subject matter that is described and claimed in the above-captioned patent application and an employee of a company, Velico Medical, Inc. (formerly ZymeQuest Inc.), which is assignee of the application and Jorgensen et al. (US 2002/0107131).
2. I have been working in the field of medical devices and blood processing for over 18 years and have been studying medical devices and blood processing for at least 22 years. I am currently Vice President of Operations of Velico Medical, Inc. Velico Medical, Inc. is a leading supplier of medical devices for the blood processing field. My experience in these industries and in this field has been a hands-on and consultant approach which has allowed me to identify the issues that the industry struggles with on a daily basis both during development and on the

manufacturing floor. I have a Master of Science degree in Mechanical Engineering from Worcester Polytechnic Institute in Worcester, Massachusetts.

3. I have read and understand the rejection of claims 1-6, 8-18, 20-29, 34, 49, and 51 under 35 U.S.C. § 102(b) as being anticipated by Jorgensen et al. (US 2002/0107131) (hereinafter Jorgensen), the rejection of claims 35-38 under 35 U.S.C. 103(a) as being unpatentable over Jorgensen, the rejection of claims 30, 32, and 33 under 35 U.S.C. 103(a) as being unpatentable over Jorgensen in view of Schultz (US 3,982,691), and the rejection of claim 50 under 35 U.S.C. 103(a) as being unpatentable over Jorgensen. Specifically, the Office Action alleges that Jorgensen discloses “a first mating portion positioned adjacent the central opening, along the interior surface of the first side, and extending in a direction perpendicular to the interior surface, and, in cross-section, including a raised shape (for example 100) the mating portion integrally formed (see [0043]) for mating in a cooperative arrangement with a corresponding mating portion of a hub (20,60,104) and the raised shape of opposing an interior surface of the second side (see Fig. 11).” (Office Action dated 07/16/2009, page 3).

4. I have read and understand Jorgensen et al. (US 2002/0107131) (hereinafter Jorgensen). I am an inventor of the subject matter that is described and claimed in Jorgensen. Jorgensen describes centrifuge processing bags that include “an outer expressor bag 96, an inner processing bag 98, outer weld rings 100, inner weld rings 102 and hub 104.” (Jorgensen, paragraph 0050, see also Figures 7, 11, and 12). As illustrated in Figures 11 and 12 of Jorgensen, the assembled processing bag utilizes the weld rings 100 and 102 to secure the bags 96 and 98 to the hub 104. Jorgensen describes locking the bags onto the hub utilizing the weld rings. (Jorgensen, paragraphs 0044, 0011, and 0013).





Further, Jorgensen describes that “[e]ach processing or expressor bag is comprised of a flexible compartment, a central hub and weld rings for connecting the flexible compartment to the central hub. (Jorgensen, ¶0043). As illustrated FIG. 12, showing an exploded perspective view of a processor bag within a bag embodiment (i.e., assembly), the weld rings 100 are illustrated as separate components from either processing bag 96, 98. They may be part of the assembly, but they are not part of the bag. Thus, the weld rings are not integral to either of the expressor or processing chambers. Rather, the weld rings are separate and part of an assembly that also includes the hub. (Id., see for example, ¶0047).

5. An important feature of the present application is that the claimed a first mating portion that includes "at least one or a raised or recessed shape with respect to the interior shape" (e.g., essentially a half of an o-ring seal) or "the first mating portion opposing an interior surface of the second side" of the bag provides a mechanical mechanism for holding the bag onto the hub while the hub is rotating. It is very important during centrifugal blood processing to ensure that the bag does not slip or move from the hub. Based on my experience and knowledge of Jorgensen as an inventor, Jorgensen does not provide this important feature of the present application because the bags described in Jorgensen are secured by the weld rings and not by any type of raised or recessed shape.

As a result, the bags described in Jorgensen are susceptible to slippage at the joint between the bag and the hub in the presence of centrifugal forces. The centrifugal forces experienced by the fluid-filled bag pull the Jorgensen bags away from the hub. In contrast, the first mating portion in the present application includes "at least one of a raised or recessed shape with respect to the interior surface" and opposes "an interior surface of the second side." Thus, the shape in the present application provides a mechanical mechanism for holding the bag onto the hub while the hub is rotating. In other words, the position of the first mating portion opposite an interior surface of the second side provides for a mechanical mechanism for preventing slippage of the bags away from the hub, thereby preventing leakage.

6. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent resulting therefrom.

Jan 15, 2016  
Date

  
Keith Rosiello